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(51) INT CL⁴
A61B 5/00

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(56) Documents cited
EP A2 0136247 US 3974491
"Biochemical measurements: pressure on skin" a
demonstration by the Oxford Orthopaedic
Engineering Centre at the "Physics at Work"
exhibition held at Oxford Polytechnic, 15 to 17 July
1986

(58) Field of search
G1N

(54) Measurement of pressure at an interface

(57) Localised pressure at an interface, for example that on the skin surface of a bed-bound invalid, is measured by means of a fluid-filled cell 1. coupled to a pressure transducer 6. An oil filled "bubble" 24' may be connected by a tube 20' to a piezo electric sensor for continuous measurement. Alternatively measurements may be taken at short intervals using a similar bubble (24) containing a pair of contacts (26). A compressor 2 inflates the bubble until the contacts open. Air is then exhausted through a valve 5 until the contacts close, whereupon a pressure reading is taken. A control means 8 records the signal from the transducer at predetermined time intervals and generates desired parameters such as a sub capillary pressure factor which indicates the proportion of the time for which the pressure is below certain predetermined values, and a discomfort factor which indicates the amount of time for which the pressure exceeds certain predetermined values.

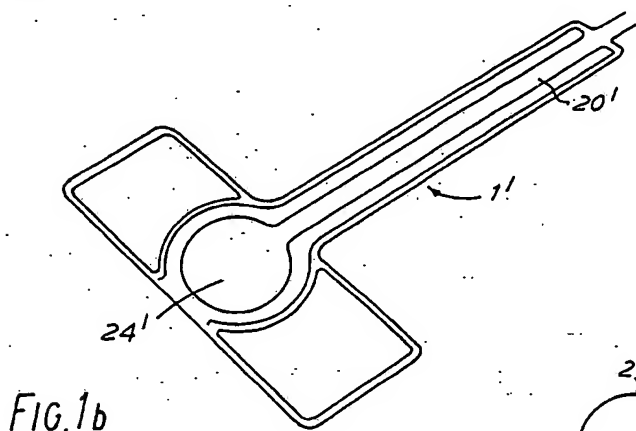


FIG. 1b

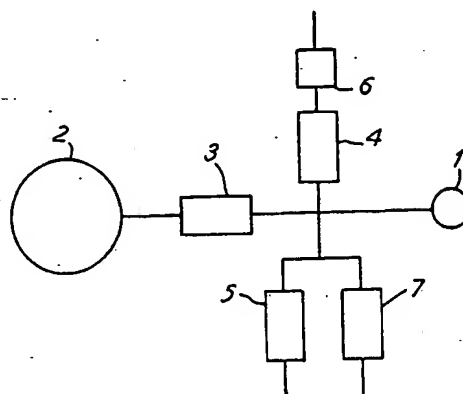


FIG. 2

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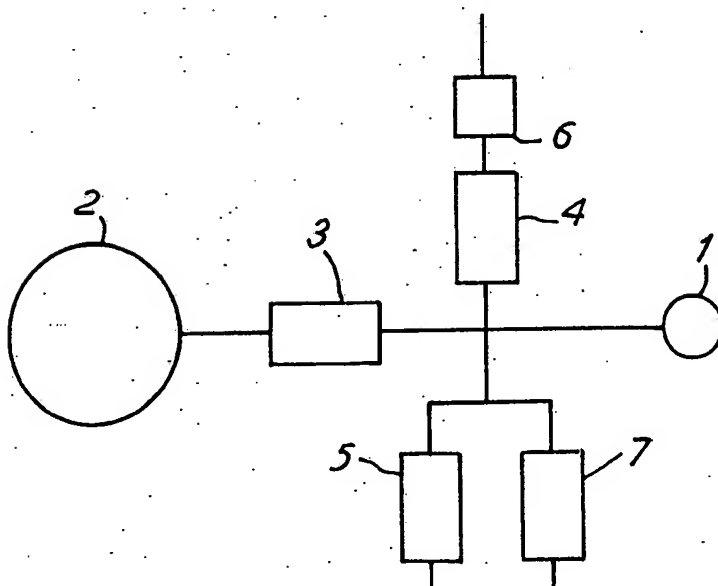
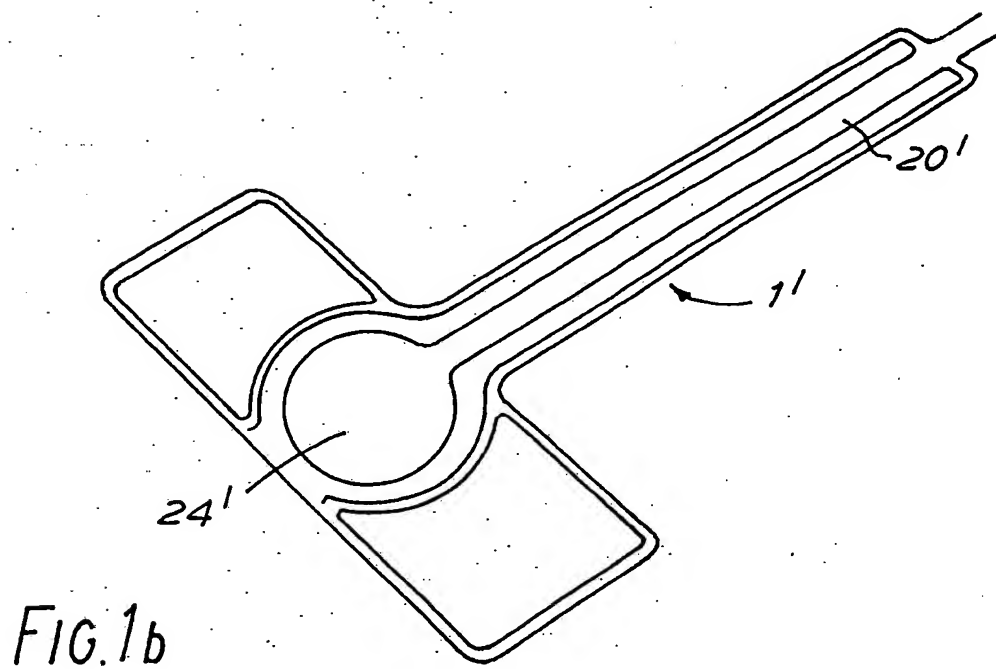
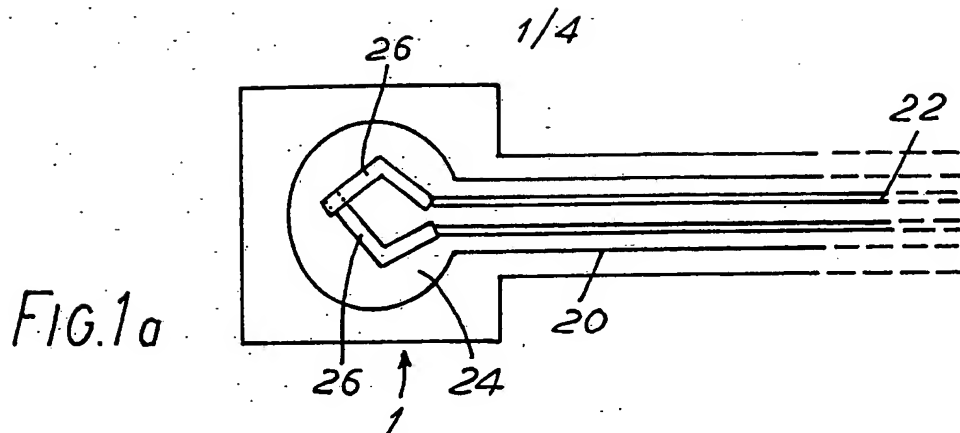


FIG. 2

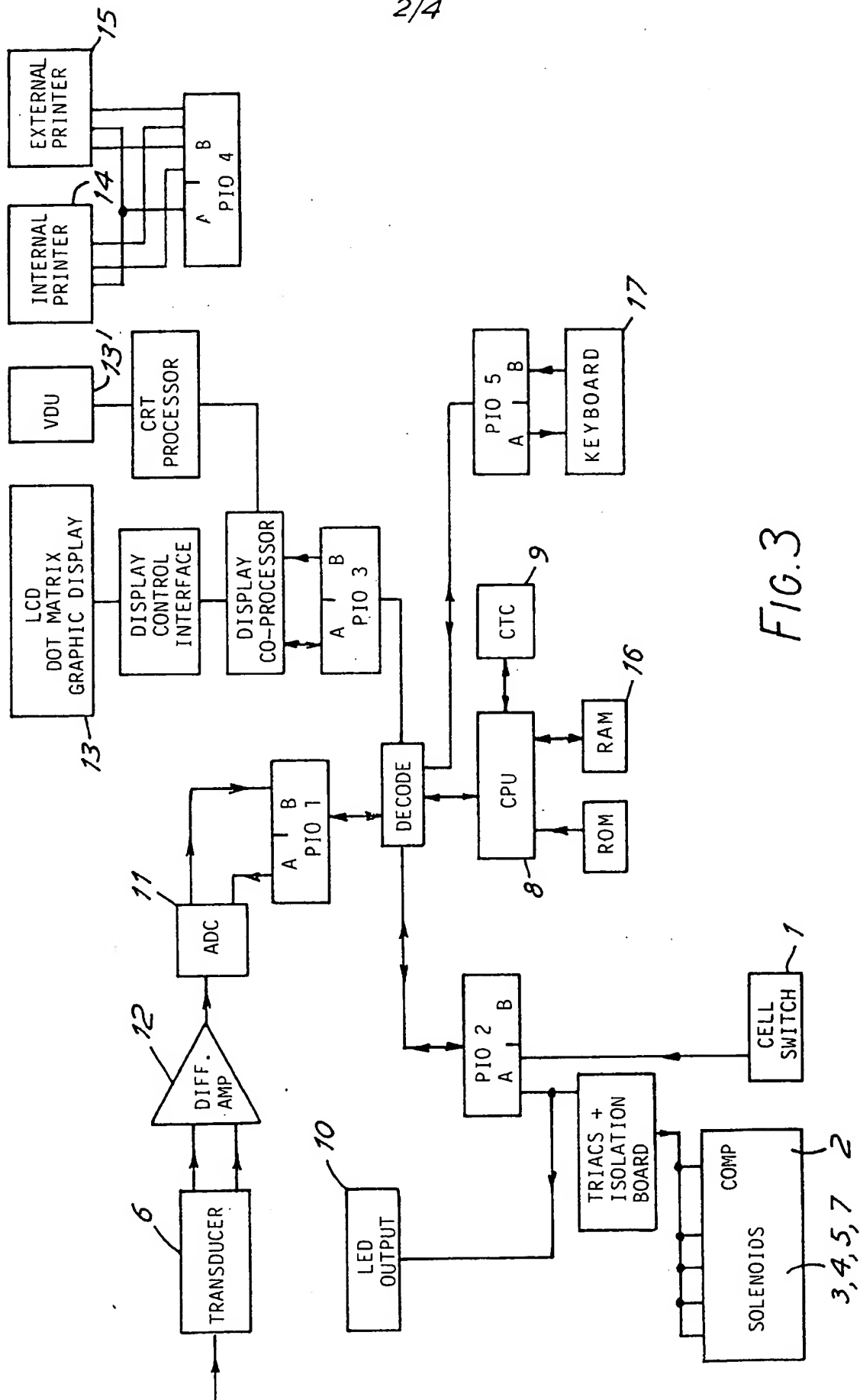


FIG. 3

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PATIENTS NAME: ALISON.

POSITION: TROCHANTER.

WEIGHT: 87 lbs.

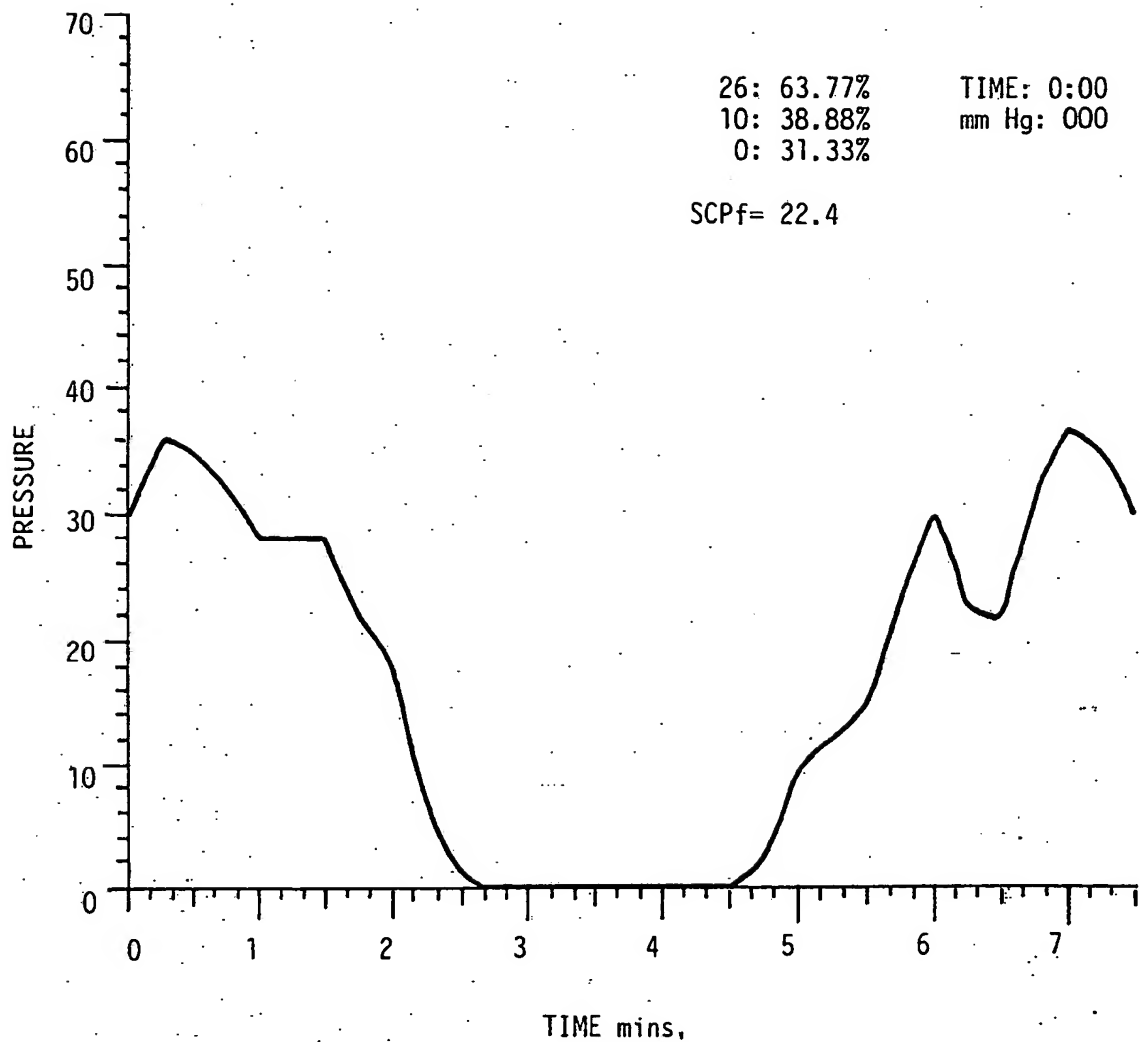


FIG. 4a

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PATIENTS NAME: ANGUS

POSITION: SACRUM SITTING 60 degree inclination MK 3. ROTOR.

WEIGHT: 175 lbs.

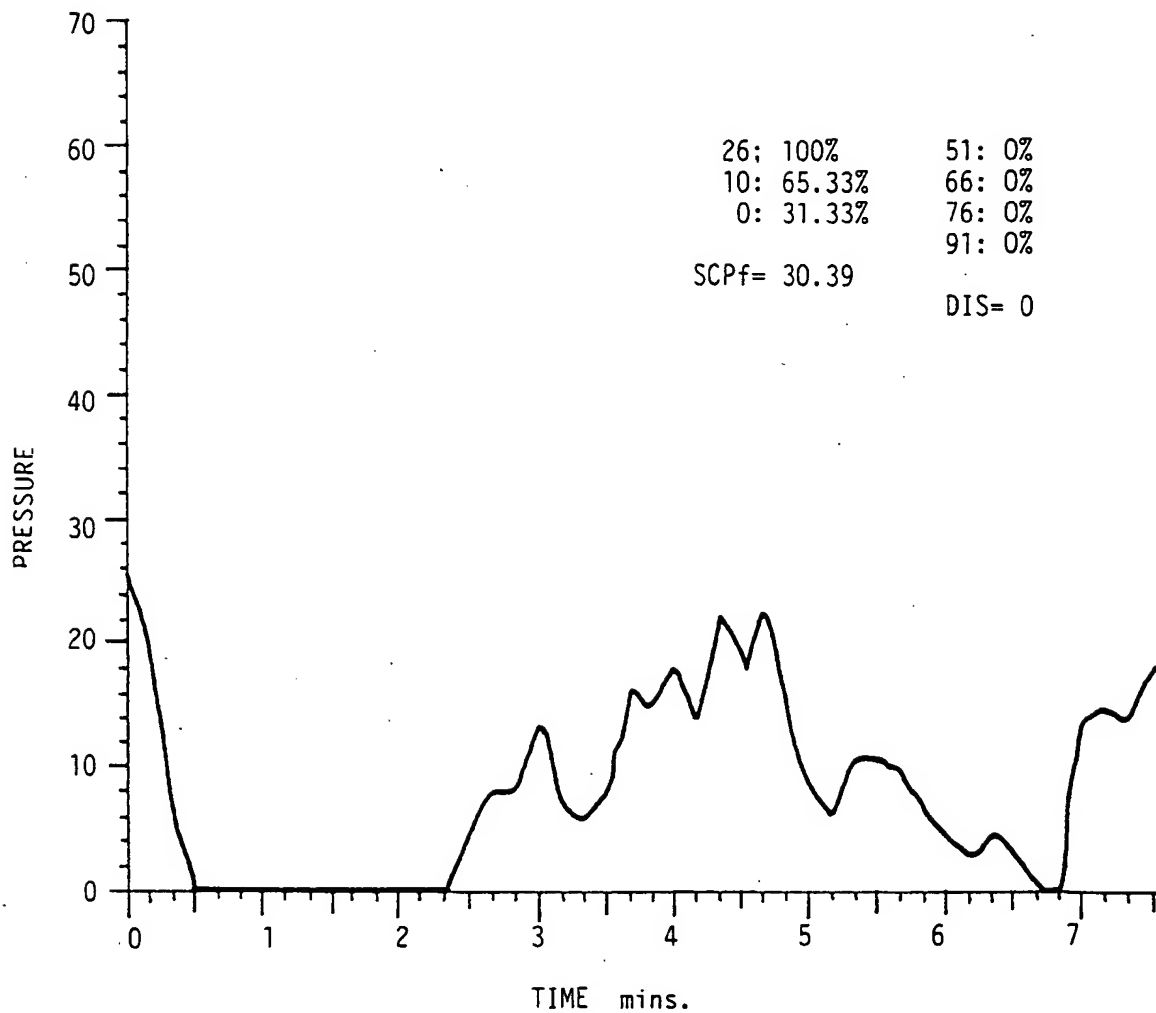


FIG.4b

MEASUREMENT OF PRESSURE

The present invention relates to an automated method of pressure measurement and apparatus therefor, for example, an apparatus for automatically measuring localised pressure on the skin surface such as that of a bed-bound invalid, or under a compression bandage or other surgical or remedial dressing or application.

Chronically ill individuals, who are bed-bound, frequently suffer from pressure sores as a result of pressure on those parts of the body which rest against the mattress and which therefore take the patient's weight. Occlusion of blood and lymph vessels results in starvation of nutrients, the non-removal of toxic waste products from pressure bearing areas of tissue and consequent development of a sore. Several different designs of air-filled mattresses have been produced to try to alleviate this problem and particularly successful have been the so-called "alternating pressure mattresses", for example that described in GB 1,595,417. In these mattresses the pressure exerted on parts of the body in contact with the inflated mattress constantly changes as the air-filled cells of the mattress alternate in supporting the patient, and the aim is that pressure on any part of the body should for much of the time be substantially below average capillary blood pressure, which ranges from 10-32mm Hg according to a patient's clinical condition.

In order to assess the pressure on a particular part

of a patient's body an electro-pneumatic interface pressure cell, operated manually using a hand pump is generally used. The pressure cell, which is generally placed beneath the appropriate part of the patient's anatomy comprises a plastic bubble containing a pair of electrical contacts. By operating a hand pump the bubble is inflated and the contacts forced apart. This forcing apart of the contacts is accompanied by the extinguishing of an LED on the hand-held unit which additionally comprises a pressure gauge and the hand pump. Air is then expelled from the bubble by the pressure of the patient's body; the needle of the pressure gauge falls and, when the electrical contact is remade the LED illuminates and the operator then closes a valve on the unit, to prevent further outflow of air, and reads the pressure from the gauge.

This method has a number of disadvantages. It depends for its accuracy on the experience and reaction time of the operator, is slow to operate, is inaccurate at low pressures or if the patient moves when the reading is being taken and is unsuited to measuring cyclically varying pressure and therefore for assessing the performance of an alternating pressure system.

The aim of the present invention is to automate electro-pneumatic or hydraulic measurement of pressure at an interface. It is desirable to provide an apparatus which will sample pressure quickly and at regular time intervals. Furthermore, it is desirable to provide a

system which will produce a numerical value for each mattress-patient, or mattress-body part combination tested, so that, by comparison of these numerical values, it is possible to compare the performance of different mattresses and to identify patients who are at high risk of developing pressure sores.

In one aspect the invention provides a pressure measuring apparatus for measuring the pressure at an interface, said apparatus comprising a fluid-containing cell having a wall portion which is urgeable by externally applied pressure to apply pressure to the fluid within the cell; the cell being adapted to be located at the interface where pressure is to be measured so that said wall portion is urgeable by the pressure to be measured which thereby influences the pressure of the cell fluid; and pressure transducer means coupled to the cell for deriving an electrical signal indicative of the cell fluid pressure.

In one type of embodiment, the cell or a cell portion is adapted to lose fluid when subjected to the interface pressure, the cell or portion undergoing deflation or compression; the arrangement being such that a signal indicative of cell fluid pressure is automatically determined when the deflation or compression of the cell reaches a predetermined degree. Thus the cell may be of the type whose manual operation is described above. In one embodiment of the present invention, the compression of such a cell brings the electrical contacts together; and

this may automatically actuate the transducer which produces the electrical signal. The cell may be filled with air. It may be re-inflated by means of a compressor.

The escape of fluid from the pressure cell may be regulated by a slow-release valve, controllable by the electronic circuitry. Another valve, also operable by the electronics may regulate the influx of fluid to the cell. The preferred method of obtaining instantaneous pressure detection is to provide an electronically operable valve between the cell and a pressure detector. The deflation of the cell to its predetermined value causes the closing of the valve, so that the pressure between the valve and the pressure detector is then fixed at the pressure of the cell when the electronically operable valve is closed.

In a different type of embodiment, the time when a signal is derived does not depend on the deflation of the cell, but may be selectable at will and/or a signal may be derived continuously. A transducer is in communication with the cell fluid, and is actuable to derive a signal. Suitably the cell fluid is substantially incompressible, e.g. an oil or water. The cell may be, or form part of, a closed system.

In a further aspect the invention provides a method for providing data relating to the pressure at an interface comprising providing a fluid-containing cell having a wall portion which is urgeable by externally applied pressure to apply pressure to the fluid within the cell, pressure

transducer means coupled to the cell for deriving an electrical signal indicative of the cell fluid pressure and signal processing means coupled to said pressure transducer means to receive electrical signals from it; locating the cell at the interface so that said wall portion is urgeable by the pressure to be measured which thereby influences the pressure of the cell fluid; and processing the signals received by said signal processing means to derive desired data relating to the pressure at the interface.

In a development of the above systems, there is provided a pressure measuring apparatus as described above and having control means coupled to the pressure transducer means to receive said electrical signal therefrom, said control means comprising timer means and signal processing means controllable thereby to receive said electrical signal from the transducer means at predetermined intervals; said signal processing means including memory means and being adapted to record the signals in the memory means as pressure/time data; to determine from said data time fractions when pressure is within predetermined ranges; and to derive from said time fractions desired parameters related to the pressure variation at the interface. In the case of the pneumatic system the cell is re-inflated between measurements.

It is desirable that the electronic circuitry should facilitate computation of a single numerical value, the value depending on the way in which the interface pressure

varies with time. To this end it is preferable to include in the electronic circuitry a central processing unit (CPU), with an associated counter timer chip (CTC).

In embodiments involving a compressor the CPU also sends signals to the compressor at regular and precisely timed intervals. Signals from the CPU are responsible for valve closure and opening so that valves may be closed extremely rapidly at the appropriate times.

The CPU computes the single numerical value which, preferably, indicates the amount of time for which the pressure is below certain predetermined values. The CPU first generates a graph based on a series of detected pressures, then analyses the result into a plurality of pressure/time bands, i.e. bands in which the pressure is below predetermined values. From those pressure/time bands a single numerical value can be generated.

The CPU may also compute, in a similar way, a further numerical value which indicates the amount of time for which the pressure is above certain predetermined values.

It is also preferred that the CPU output and the information it receives on the variation of pressure with time, and also the numerical value which it has computed, is fed to a display screen such as a conventional monitor, VDU, or LCD. Optionally, a printer may also be provided to convert the display into hard copy.

A keyboard may also be provided for entering details of each interface (i.e. usually patient and mattress

combination) tested.

Two embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings in which:

Fig. 1a shows a plan view of a fluid containing cell of a pressure measuring apparatus according to a first embodiment of the invention;

Fig. 1b shows a plan view of a fluid containing cell according to a second embodiment of the invention;

Fig. 2 is a block diagram indicating the way in which the pressure measuring device, in this case an interface pressure cell as shown in 1a, is connected to a compressor and solenoid valves according to one embodiment of the invention;

Fig. 3 is a block diagram showing the connections of the central processing unit to the pressure cell, displays and keyboard;

Figs. 4a and 4b show exemplary displays as printed by an external printer.

In applications where the pressure exerted on a patient by a mattress is to be measured the pressure measuring device may be an air-inflatable pressure interface cell for example as shown in Fig. 1a. Fig. 2 indicates the way in which an air-inflatable pressure interface cell 1 may be inflated by a compressor 2 and the pressure exerted on the cell 1 measured, according to a first embodiment of the invention.

The pressure interface cell 1 is of the type which is conventionally used for non-automated measurement of interface pressure and comprises a flat plastic tube 20 through which run a pair of copper wires 22. These terminate at electrical contacts 26 in a "bubble" 24 at the end of the plastic tube 20. The bubble can be inflated by connection of an air supply from the compressor 2 at the end of the plastic tube 20 and the electrical contacts 26 are forced apart. When the bubble is deflated the contacts 26 'make' to complete an electrical circuit but on inflation of the bubble the contacts 26 are forced apart to break the circuit.

The pressure interface cell 1 is taped to, or inserted beneath, the patient's body so that the bubble 24 is positioned on the part of the patient's body where the pressure is to be measured. When the cell is taped, the tape is affixed to the pressure interface cell 1 at a position away from the bubble 24 so that it does not interfere with the pressure measurement.

When a pressure measurement is to be taken solenoid valves 3 and 4, respectively between the compressor 2 and the cell 1, and between the cell 1 and a transducer 6, are opened and the compressor 2 urges air into the interface cell 1. The compressor 2 may be a small one such as that manufactured by Nitto Kohkai and having a power rating of 15W. Operation of the compressor 2 and opening of the solenoid valves 3,4 are under the control of a central

processing unit (see later). Inflation of the bubble of the interface cell 1 causes the electrical contacts therein to be broken and solenoid 3 is then shut. The bubble of the interface cell 1 then gently deflates through the slow exhaust valve 5 to atmosphere. The speed of deflation depends both on the nature of the slow exhaust valve 5 and on the pressure which is being exerted on the cell 1.

As air gradually leaks from the cell 1 a point is reached at which the contacts within the bubble 'make'. When the circuit is thus completed, the solenoid valve 4 is then closed. Such closure of a valve 4 occurs within microseconds of making of the contacts. Residual pressure in the line between the valve 4 and the transducer 6 is then measured and is equal to the pressure on the interface cell 1 at the time the contacts meet.

After the pressure measurement has been taken the slow exhaust valve 5 and fast exhaust valve 7 are both opened and the cell 1 and lines interconnecting the various components evacuated. The cycle then starts again.

Fig. 3 indicates the way in which the system described above is operated under the control of a central processing unit (CPU) 8.

The CPU 8 sends signals to the solenoid valves 3,4, and the exhaust valves 5,7 and to the compressor 2. The counter timer (CTC) 9 linked to the CPU 8 enables it to send signals to the compressor 2 at regular and accurate time intervals. Thus, at ten second intervals (which are

accurate to 10ms - i.e. one half cycle of mains voltage), the CPU sends a signal to the compressor 1 and to the solenoid valves 3 and 4. It then monitors the circuit making and breaking in the interface cell 1, sends signals to close valve 4 and later to open valve 7 to evacuate the system. The CPU also controls the illumination of LEDs on an output board 10. Those LEDs indicate which of the valves 3,4,5 and 7 are open at a particular time. For example by provision of appropriate dual colour LEDs a green light will indicate that a particular valve is open while red indicates that it is shut.

The pressure existing in the line connecting the solenoid valve 4 and the transducer 6, when the contacts in the interface cell 1 make and valve 4 is closed by a signal from the CPU, is converted into an electrical signal by the transducer 6. That signal is converted by an analogue to digital converter (ADC) 11, after being amplified one hundred and forty times by a differential amplifier 12, to a signal representing a digital number of from 0 to 255. This number signal is fed to the CPU 8 where it is processed, sent for display and/or stored.

As mentioned above a pressure reading is recorded by the CPU 8 every two seconds. The processor takes 225 readings which are then displayed either on a conventional monitor or on a liquid crystal display dot matrix graphic display 13 as a plot of pressure against time. Thus, the pressure on the interface cell at two

second intervals over a $7\frac{1}{2}$ minute period is recorded. This corresponds to the time for one complete cycle of the alternating pressure mattress described in GB 1,595,417. However other time periods such as of 1-15 minutes duration can be programmed, and the number of readings taken could be adjusted if it were desired to monitor the performance of an alternating pressure mattress having a different cycle time.

As was explained above it is desirable when comparing the performance of different mattresses or when evaluating the risk to a particular patient who may have marked bony protuberances, for example, or particularly low capillary blood pressure, to be able to compute a factor which will enable mattresses and patients to be compared. In particular it is desirable to know for what proportion of the time the pressure on the patient falls below certain predetermined values. Preferably, the pressure on the patient should be significantly below his actual capillary blood pressure for substantial time periods, especially because capillary blood pressure tends to be, or is deliberately, lowered in illness below normal. In the apparatus of the present invention the CPU 8 is employed to compute a sub-capillary pressure factor SCPF as follows.

The processor 8 examines the displayed plot and converts it into 225 points, recording a value of the pressure for each point. By then looking for points corresponding to pressures below 26mm Hg it computes the

percentage of the total 7½ minute period for which the pressure on the patient is below 26mm Hg. It then looks for points below 10mm Hg and computes the percentage of the time spent below that pressure. Finally, the percentage of the time spent at zero pressure on the patient is calculated. Pressures below 26mm Hg are assigned a points value of 6 (because 26mm Hg is 6mm Hg below the normal upper limit of average capillary pressure), pressures below 10mm Hg are assigned a value of 22 in the same way and zero pressures score a maximum points value of 32. The SCPF is then given by

$$\text{SCPF} = 6 \times (\text{fraction of time below 26mm Hg}) + 22 (\text{fraction of time below 10mm Hg}) + 32 (\text{fraction of time at zero pressure}).$$

Thus for example if the pressure on a particular part of the patient's body is below 26mm Hg for 60% of the time, below 10mm Hg for 40% of the time and at zero for 25% of the time then

$$\begin{aligned} \text{SCPF} &= 6 \times 0.6 + 22 \times 0.4 + 32 \times 0.25 \\ &= 3.6 \quad + 8.8 \quad + 8.0 \\ &= \underline{20.4}. \end{aligned}$$

The various percentages, together with the computed value of the SCPF are displayed with the plot on the display 13.

In a similar way, it is possible to calculate and display a discomfort factor corresponding to the particular variation of pressure with time. In this case, penalty

points are assigned according to the fraction of time spent above preselected pressures. There is no penalty score for interface pressures of between 32 and 50mm Hg, while 10 points are assigned for pressures of 51-65mm Hg, 20 points for 66-75mm Hg, 40 points for pressures of 76-90mm Hg and 60 points for pressures of 91mm Hg upwards. The point values are multiplied by the time fractions as above.

It will be apparent that by appropriate programming a variety of factors may be computed and displayed.

There is also provision for a printer. This may for example be a small "internal printer" 14 which is built into the unit, adjacent to the display or optionally may be an external printer 15, such as an EPSON. The internal printer 14 provides hard copy on the spot, but the plot produced is small, for example only 10cm high. An external printer is useful for providing larger printouts. The CPU includes 32K of static RAM 16 which enables data from each patient/mattress to be stored and accessed later.

Figs. 4a and 4b show typical plots from an EPSON printer showing the variation of pressure with time when the interface pressure cell 1 is placed directly externally to the trochanter of a patient lying on the alternating pressure mattress described in GB 1,595,417. Pressure appears on the ordinate while time in minutes is on the abscissa. Details of the patient, entered by keyboard 17 are displayed at the top left of the plot while percentages of time spent below selected pressures or at zero pressure,

together with the SCPF are shown at the top right. A discomfort factor has been calculated for the plot in Fig. 3b and is also displayed at the top right.

The entire apparatus may be made extremely compact and, where a LCD dot matrix display rather than a conventional monitor is used for display, would fit into an attache case. A VDU can also be used for display. It is envisaged that the system would be powered from the mains after appropriate stepping down of the voltage by transformer. Alternatively it is feasible to power it using sealed lead acid cells or Nicad batteries.

In an alternative embodiment of the invention shown in Fig. 1b the pressure-interface cell 1' is filled with a hydraulic fluid and does not have electrical contacts within it. The cell, connecting tubing and transducer form a closed system, and the interface pressure is measured by transmission of pressure through fluid in the pressure interface cell and connecting tubing to the transducer.

The cell 1' is of plastics, suitably of PVC, and includes a bubble 24' which is about 2cm across. The 'bubble' 24' is filled with a hydraulic fluid such as oil or water and may be as little as 2mm thick.

The 'bubble' 24' is connected via a tube 20' to a transducer, such as a piezoelectric solid state pressure sensor.

Hydraulic fluid also fills the tube 20'. A small air bubble in the hydraulic fluid facilitates thermal expansion

of the fluid for maximum accuracy of pressure measurement. The transducer converts the fluid pressure in the line from the pressure cell into an electrical signal which can be processed in an analogous way to that described above for the pneumatic arrangement. In this case the signal at the transducer is amplified about 70 times by the differential amplifier 12 before conversion in the ADC 11 to a digital number. The number signal is fed to the CPU 8 and is processed as described above to obtain a graph and a sub-capillary pressure factor or a discomfort factor.

Advantageously, the programming of the processor is arranged so that the pressure readings taken are automatically adjusted to allow for the pressure of the head of liquid in the tube 20'. This pressure varies according to the height at which the cell is placed. Therefore, the cell is held at the height at which it will be used and an initial pressure reading is recorded. This reading is then automatically taken into account to correct each reading of a subsequent set of readings in which the cell is attached to the skin surface of a patient.

The hydraulic arrangement has several advantages over the air-inflatable one described above. Most of these arise because it is no longer necessary to inflate and deflate the cell to obtain a pressure measurement. Because the system is sealed there is no need to use compressors or valves. Thus the size, complexity, and expense of the

system can be reduced. The CPU determines at what time intervals the pressure should be monitored, and processes the data collected but is not required to supply signals for activating the valves or activating the pressure sensing means after contact making in the pressure cell since both valves and contacts are dispensed with. Thus, those parts of the block diagram of Fig. 2 showing connection to the cell switch, and compressors are not applicable.

A further advantage of the hydraulic system is that pressures can be measured at much shorter time intervals. For example, when a compressor is used, together with an inflatable pressure-interface cell, the pressure can only be measured every two or three seconds, or at longer intervals. With the hydraulic cell, the pressure could be read every 10 microseconds but would typically be read every 1 second. In this way a resolution of 1 second and better can be achieved.

This arrangement may be run from the mains or from a cell or battery as described above. It is particularly well suited to running from a battery because it has a very low power requirement, there being no compressors to run. The system may be operated continuously for twenty to twenty four hours when run off a solid gel battery.

In a development of the pressure measuring apparatus including a hydraulic fluid filled cell, a single microcomputer chip can be used to process signals from the

transducer. The microcomputer provides a pressure reading at specified time intervals but does not use the data to calculate a sub-capillary pressure factor. An apparatus of this type is particularly useful to allow nursing staff to monitor pressure continuously over an extended time period. Because of its small size the apparatus is particularly useful for monitoring post-operative pressure under dressings.

CLAIMS

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1. A pressure measuring apparatus for measuring the pressure at an interface, said apparatus comprising a
5 fluid-containing cell having a wall portion which is urgeable by externally applied pressure to apply pressure to the fluid within the cell; the cell being adapted to be located at the interface where pressure is to be measured so that said wall portion is urgeable by the pressure to be
10 measured which thereby influences the pressure of the cell fluid; and pressure transducer means coupled to the cell for deriving an electrical signal indicative of the cell fluid pressure.

2. A pressure measuring apparatus according to claim 1
15 having control means coupled to the pressure transducer means to receive said electrical signal therefrom, said control means comprising timer means and signal processing means controllable thereby to receive said electrical signal from the transducer means at predetermined
20 intervals; said signal processing means including memory means and being adapted to record the signals in the memory means as pressure/time data; to determine from said data time fractions when pressure is within predetermined ranges; and to derive from said time fractions desired
25 parameters related to the pressure variation at the interface.

3. A pressure measuring apparatus according to claim 2 wherein the memory means stores weighting factor data

relating to said predetermined ranges; and the signal processing means is adapted to multiply said time fractions by respective weighting factors of said data to provide weighted time fractions; and to multiply said weighted time 5 fractions together to obtain said desired parameters.

4. A pressure measuring apparatus according to claim 1 wherein the wall portion is urgeable to reduce the volume of the cell which is adapted to lose fluid in response thereto; the means for deriving a pressure-indicative 10 signal being adapted to derive said signal automatically when the loss of fluid from the cell reaches a predetermined degree.

5. A pressure measuring apparatus according to claim 4 wherein said cell has a second wall portion opposed to said 15 urgeable wall portions and said urgeable and second wall portions are relatively displaceable to alter the cell volume; and wherein the cell contains a pair of electrical contacts arranged to be relatively moveable on relative displacement of said cell wall portions; the cell being 20 inflatable to a conformation in which the contacts are apart and deflatable to a predetermined degree at which the contacts make; and wherein means are provided for detecting the making of the contacts and, in response to said detection, actuating the means for deriving said 25 signal indicative of cell fluid pressure.

6. A pressure measuring apparatus according to any one of claims 1, 4 or 5 wherein the cell has an outlet for said loss of fluid; a slow release valve for controlling fluid

flow being provided in said outlet; and wherein the means for deriving a pressure-indicative signal are spaced from the chamber and in fluid communication therewith via conduit means; a second outlet valve being provided in said 5 conduit means; and wherein there are control means for actuating closure of said second outlet valve, said control means being arranged to actuate closure in response to the making of said contacts.

7. A pressure measuring apparatus according to claim 6 10 wherein the control means comprises electronic control circuitry having first input means for receiving a first input signal indicative of the making of the contacts, and second input means for said signal indicative of cell fluid pressure; and processing means for acting on receipt of 15 said first input signal to provide a first output signal for actuating said second outlet valve, and to receive via said second input means said signal indicative of cell fluid pressure.

8. A pressure measuring apparatus according to any one of 20 the preceding claims wherein the fluid is air.

9. A pressure measuring apparatus according to any one of claims 1 to 3 wherein the cell provides a closed system and the pressure transducer is arranged to sense the pressure of fluid in the cell continuously; and wherein control 25 means are provided coupled to the pressure transducer and arranged to receive and display said electrical signals indicative of cell fluid pressure at predetermined intervals.

10. A pressure measuring apparatus according to any one of claims 1 to 7, or 9 wherein the cell fluid is a liquid.

11. A pressure measuring apparatus substantially as herein described with reference to and as illustrated in the 5 accompanying drawings.

12. A method for producing data relating to the pressure at an interface comprising providing a fluid-containing cell having a wall portion which is urgeable by externally applied pressure to apply pressure to the fluid within the 10 cell, pressure transducer means coupled to the cell for deriving an electrical signal indicative of the cell fluid pressure, and signal processing means coupled to said pressure transducer means to receive electrical signals from it; locating the cell at the interface so that said 15 wall portion is urgeable by the pressure to be measured which thereby influences the pressure of the cell fluid; and processing the signals received by said signal processing means to derive desired data relating to the pressure at the interface.

20 13. A method according to claim 12 wherein a multiplicity of electrical signals indicative of cell fluid pressure at respective different times are received by the signal processing means and processed thereby to derive desired data relating to the variation of pressure with time.

25 14. A method according to claim 12 or claim 13 wherein said cell has a second wall portion opposed to said urgeable wall portions and said urgeable and second wall portions are relatively displaceable to alter the cell

volume; and wherein the cell contains a pair of electrical contacts arranged to be relatively moveable on relative displacement of said cell wall portions; the method comprising (i) inflating the cell to a conformation in
5 which the contacts are apart and; then (ii) deflating it to a predetermined degree at which the contacts make; and (iii) detecting the making of the contacts and, in response to said detection, actuating the means for deriving said signal indicative of cell fluid pressure; said steps (i) to
10 (iii) being repeated cyclically.

15. A method substantially as herein described with reference to and as illustrated in the accompanying drawings.

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